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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 99D–2215]**

# International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); VICH GL10 Draft Guidance on "Impurities in New Veterinary Drug Substances;" Availability; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH GL10 draft guidance for industry entitled "Impurities in New Veterinary Drug Substances" is intended to assist in developing registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

**DATES:** Submit written comments (*insert date 30 days after date of publication in the* **Federal Register**); FDA must receive comments before the deadline in order to ensure their consideration at the next VICH committee meeting, but the agency will accept comments after the deadline.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in the heading of this document.

Copies of the draft guidance entitled "Impurities in New Veterinary Drug Substances" may be obtained on the Internet from the CVM home page at "http://www.fda.gov/cvm/fda/TOCs/guideline.html". Persons without Internet access may submit written requests for single copies



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of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

**FOR FURTHER INFORMATION CONTACT:**

Regarding VICH: Sharon Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, E-mail ''sthompso@cvm.fda.gov''.

Regarding the guidance document: Kevin Greenlees, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, E-mail ''kgreenle@cvm.fda.gov''.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seeking scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for several years to develop harmonized technical requirements for the registration of human pharmaceutical products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the registration of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Épizooties. The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/ New Zealand, one representative from the industry in Australia/ New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative participates in the VICH Steering Committee meetings.

At a meeting held on October 20 through 22, 1998, the VICH Steering Committee agreed that the draft guidance document entitled ''Impurities in New Drug Substances'' should be made available for public comment.

This draft guidance is intended to provide guidance for registration applications on the content and qualification of impurities in new drug substances intended to be used for new veterinary medicinal products produced by chemical syntheses and not previously registered in a region or member state. Comments about this draft guidance will be considered by the FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as future guidance.

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practice regulations (62 FR 8961, February 27, 1997). For example, the document has been designated ''guidance'' rather than ''guideline.'' Since guidance documents are not binding, mandatory words such as ''must,'' and ''shall,'' and ''will'' in the original VICH

document have been substituted with ''should'' unless the reference is to a statutory or regulatory requirement. Additionally, the term(s) ''veterinary medicinal products'' and ''veterinary pharmaceutical products'' may require revision to be consistent with product terms used in other VICH guidance documents.

This draft guidance represents the agency's current thinking on the regulation of impurities in new animal drug substances. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

## II. Comments

Interested persons should submit written comments on or before (*insert date 30 days after date of publication in the* **Federal Register**) to the Dockets Management Branch (address above) regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments

are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/15/99

July 15, 1999

Margaret M. Dotzel
Acting Associate Commissioner
for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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